Remarks and Response

Remarks

Applicant confirms the previous election of claims 201-213 and 215-249 for present prosecution following the Examiner's telephone restriction, and accordingly cancels claims 33-41 and 45-63 from the present prosecution. Accordingly all claims 1-200 are now cancelled from the present matter without prejudice to ongoing prosecution of the subject matter of those claims in continuing applications. In addition, as pointed out by the Examiner, claim number 214 was omitted in the previous submission, so that the pending claims at the time of the Office Action were claims 201-213 and 215-249.

The pending claims are drawn to a method for using data associated with at least one database, wherein essential adverse event information is stored as defined, said method comprising accessing the essential adverse event information database and in a novel manner, commercializing essential adverse event information stored therein.

Claim 250 has been added to provide an independent claim wherein the product or device is medical, as suggested in passing by the Examiner. Claim 251 has also been added as dependent on claim 250. If claims 250 and 251 and the method of using Applicant's invention with regard to new adverse event data relating to a medical product or device, or when the medical product is a generic drug, respectively, are found to be allowable, dependent claims 212 and 215 which support the new claims, could be cancelled to avoid duplication.

Claims 201-213, 215-249 and 250-251 are now pending. No new matter has been added.

Response

Regarding Examiner's Response to Applicant's Previous Arguments

Applicant confirms the previous election of claims 201-213 and 215-249 for present prosecution following the Examiner's telephone restriction, and accordingly cancels claims 33-41 and 45-63 from the present prosecution. Accordingly all claims 1-200 are now cancelled from the present matter without prejudice to ongoing prosecution of the subject matter of those claims in continuing applications. In addition, as pointed out by the Examiner, claim number 214 was omitted in the previous submission, so that the pending claims at the time of the Office Action were claims 201-213 and 215-249. As suggested by the Examiner in a telephone inquiry, claim 214 is now identified as "Omitted." and to use the wording required by the Patent Office, its status is also defined as "Not Entered."

The pending claims are drawn to a method for using data associated with at least one database, wherein essential adverse event information is stored as defined, said method comprising accessing the essential adverse event information database and in a novel manner, commercializing essential adverse event information stored therein.

No changes were made to the claims, except the status of claim 214. Accordingly, no new matter has been added.

Regarding the Rejection under the Judicially Created Doctrine of Obviousness-Type Double Patenting

The Examiner has rejected Applicant's application under the judicially created doctrine of obviousness-type double patenting over Applicant's previously issued US Patent No. 6,219,674 (" the '674 patent"). In particular, the Examiner alleges that claim 201 of the present application is anticipated by claim 15 of the '674 patent, meaning that in the Examiner's opinion, "every element of claim 201" is contained in the '674 patent. However, such an assertion is incorrect because the '674 patent fails to teach each and every element of Applicant's claim 201, and therefore, fails to anticipate the presently claimed invention.

"[T]he law of double patenting is concerned only with what patents claim. "Double patenting," therefore, involves an inquiry into what, if anything, has been

claimed twice. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 23 USPQ2d 1839, 1840 (Fed. Cir. 1992) (explaining that decaffeination of coffee and recovery of caffeine, are separate, patentably distinct inventions between which there cannot be double patenting). Therefore, the only question is what is claimed in Applicant's application as compared to what was claimed in the '674 patent. According to *General Foods Corp., supra* at 1843, to determine the existence of double patenting, the first question that must be answered is: Is the same invention being claimed twice?

The answer in the present case is "No." The element of commercializing the "new essential adverse event information" stored in the database is claimed in Applicant's present invention, but it is not even suggested in the claims of the '674 patent. The cited claim 15 of the '674 patent reads:

> 15. A method for creating and using product data, said method comprising the steps of:
>
> accessing at least one adverse event data source that stores adverse event data associated with a commercially available product;
>
> analyzing said adverse event data to identify new adverse events associated with the product;
>
> creating at least one adverse event information database, said creating comprising analyzing data from said at least one adverse event data source to identify at least one new use for the product responsive to identification of at least one new adverse event associated with the product, said creating further comprising storing adverse event information, said adverse event information including said at least one new use; and
>
> commercializing adverse event information stored at said at least one adverse event information database.

As can be seen upon careful review of claim 15 of the '674 patent, the accessed database includes "at least one adverse event data source" relating to a commercially available product." When that previously recorded adverse event data in the database is analyzed in claim 15, "at least one new use for the product" is identified regarding a new adverse event associated with the product. That new use information is stored as "adverse event information," and then the stored adverse event information is commercialized.

By comparison, pending claim 201 of Applicant's present invention defines a method that is quite different from claim 15 above. Claim 201 presently reads:

> 201. A method for using data associated with at least one database, wherein essential adverse event information is stored, and wherein the data therein is derived from an analysis of data from at least one adverse event data source of previously gathered data, and identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith, wherein the database comprises stored essential adverse event information, and wherein the adverse event information includes the at least one new use or characteristic, said method comprising commercializing new essential adverse event information stored therein.

In Applicant's present application, the data that is used in the method is defined as "new essential adverse event information." As indicated in Applicant's Response to the previous Office Action, "essential adverse event information" is a defined term, beginning at paragraph 0085. "The final determination of what is 'essential' information is determined by a regulatory agency such as the FDA." See paragraph 0086. Applicant's "new adverse event information" is "essential," as further defined in paragraph 0087, specifically in terms of proprietary data.

> New adverse event information that is "essential" is of great commercial value since if this information is proprietary, for example patented in the form of a new use, it can be used to exclude potential competitors from selling a product which would require the essential information. In order for a company searching through raw adverse new uses, to maximize profits from such a search, the "essential" new uses should ideally be separated from other new uses. By limiting the protection for such new data, *e.g.*, patenting, and limiting petitions to regulatory agencies to only the "essential" new uses, a company saves time and money by avoiding expending time on adverse event information that has little commercial value.

Applicant further explains at paragraph 0094, that "[h]aving estimated the risk of an adverse event associated with a product, such as a drug, one can determine if the adverse events are essential. Several different criteria can be utilized to determine if the adverse reaction is essential," followed by a listing of non-limiting examples. By comparison, at paragraph 0095, Applicant defines an *unnecessary adverse event*, as one that "would be an essential adverse event that could be, or could have been, easily avoided. In the list that follows in paragraph 0094, a drug interaction is described as an "unnecessary adverse event," which could have been avoided by withholding one of the interacting drugs. Other such unnecessary adverse events are then listed. Paragraph

0096 describes another type of essential adverse event information, wherein risk "exceeds the benefit." Paragraph 0097 describes a third type of essential adverse event information, wherein "frequency of the adverse event is so high, or the event so severe, that [it is] a significant health concern or medical management issue" other essential adverse events in this category include marked abnormalities in laboratory values, vital signs, EKG, and seizures. Paragraph 0098 describes a fourth type of essential adverse event information, that is so well characterized that causation is generally believed to exist, such as those detected in two separate, well-controlled clinical trials, industrial chemicals that are known to cause severe adverse events. See also paragraph 0100 describing another use of Applicant's adverse event model to develop new methods of screening drugs for adverse events.

Thus, Applicant's use of the term "new essential adverse event [associated with the product or device]" refers to newly created novel information. "New" does not refer to a temporal definition, such as reference to a recent event. In fact, it is a goal of Applicant's invention to search for novel adverse events that are patentable. As a result, Applicant treats recently reported adverse events (relating to the "time" the events were recorded) as "old," since adverse events reported by others are not patentable. The claims issued in the '674 patent make no reference what-so-ever to a "new essential adverse event" as defined by Applicant's present invention. Moreover, neither information relating to a "commercially available product" in the adverse event data source, nor creating and forming an adverse event information database and "commercializing adverse event information stored" therein, referred to in claim 15 of the '674 patent, is not at all the same as a method for "commercializing new essential adverse event information" in Applicant's claim 201.

Therefore, returning the double patenting analysis, the answer to the initial question is: "No, the same invention is not being claimed twice." As a result, according to *General Foods Corp., supra* at 1843, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting?

Applicant's answer to that question is also "No." Not only does the '674 patent fail to claim or even suggest either the creation of or use of "new essential adverse event

information," Applicant's present invention fails to make any requirement that a critical element of the '674 patent be present – that the stored data is associated with a "commercially available" product. As a result, even in a two way analysis the claims of the two inventions are neither the same, nor a variation of each other. Each set of claims defines different subject matter.

Consequently, the two inventions are, in fact, patentably distinct, each claiming one or more unique elements that are not found in the other. Therefore, there is no double patenting, and Applicant's claims are neither anticipated by the '674 patent, nor does Applicant presently claim an obvious variation of the patented claims. As a result, returning to the standard set by *General Foods Corp., supra* at 1843, since the rejected pending claims of Applicant's invention define subject matter that is not an obvious variation of the '674 patent, Applicant's two inventions are necessarily patentably distinct. Moreover, since Applicant's claims are not fixed until they are finally allowed, no terminal disclaimer is needed at this time. However, Applicant will re-visit this issue, if necessary, when there is an indication from the Examiner that all pending claims are allowed or allowable. Until then, Applicant asks that this rejection be withdrawn as not only improper, but also premature.

Regarding Rejection under 35 U.S.C. §103(a)

The Examiner has rejected claims 201, 203, 205-207, 209-211, 216, 217, 220, 221, 225-228, and 231-245 under 35 U.S.C. §103(a) as allegedly being unpatentable over US Patent No. 5,726,884 ("Sturgeon"), in view of US Patent No. 6,944,776 ("Lockhart"). In making this rejection, the Examiner states that Sturgeon is "admitted prior art." Applicant is aware of no such admission, and objects to the Examiner's conclusion which is incorrect absent evidence of such an "admission." The rejection is further traversed for the following reasons.

In order to establish a *prima facie* case of obviousness three basic criteria must be met. First, there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references), when

combined, must teach or suggest all of the claim limitations – in the present situation including a method for using data from database(s) comprising essential adverse event information based upon an analysis of previously gathered data, and identifying new useful characteristic(s) or product(s) based upon the identification of *new* essential adverse event(s) associated therewith, wherein the method comprises commercializing the *new essential adverse event information.* "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991), emphasis added by Applicant.

Further, in determining the differences between the prior art and the claims, the question under 35 U.S.C. §103(a) is not whether selected differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. See, *e.g. In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976).

Applicant respectfully submits that the Examiner has erred in rejecting the cited claims under 35 U.S.C. §103(a) as being unpatentable over Sturgeon, in view of Lockhart. As a preliminary matter, it is submitted that taken as a whole, the combination of Sturgeon and Lockhart fails to disclose each and every element of claim 201, or the cited claims dependent thereon. Further, even if the combination of Sturgeon and Lockhart were to disclose each element of claim 201, it is submitted that the Examiner has not succeeded in demonstrating motivation to modify or combine references as suggested. Thus, the Examiner has failed to provide evidence supporting a reasonable expectation of success in producing and using the referenced Sturgeon patent to achieve Applicant's claimed method for using data from database(s) comprising essential adverse event information based upon an analysis of previously gathered data, and identifying new useful characteristic(s) or product(s) based upon the identification of new essential adverse event(s) associated therewith, wherein the method comprises commercializing the new essential adverse event information, as recited in present claim 201.

A. The Obviousness Rejection over Sturgeon.

In making the rejection, the Examiner has relied upon Sturgeon for disclosing "a method for using data associated with at least one database, wherein essential adverse event information is stored, and wherein the data therein is derived from an analysis of

data from at least one adverse event data source of previously gathered data, and identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith, wherein the database comprises stored essential adverse event information, and wherein the adverse event information includes the at least one new use or characteristic," citing col. 8, lines 23-25. However, the Examiner's statement is not a description of Sturgeon's invention. Rather, the Examiner has merely reiterated the preamble of Applicant's claim 201, but has said nothing about the Sturgeon patent or what it actually teaches.

The Sturgeon patent relates to automation, integration, management and regulatory review of environmental, health and safety information as it pertains to the manufacture, process, use, handling, and/or transport of chemical products and/or by-product wastes that are considered hazardous to humans or to the environment. According to the summary of the invention, Sturgeon provides a hazardous substance management system "that, in one integrated system, provides eight functional groupings and a relational database schema or database design that integrates three, four, five, six, seven or eight of these functional groupings and allows them to share or exchange information on hazardous substances for in-house and regulatory compliance-related functions." Sturgeon states at the beginning of the Detailed Description that FIG. 1 provides "a schematic overview of the system."

FIG. 1 and the description provides a system which is organized into seven or eight functional groupings in particular embodiments: (1) a Hazardous Materials Index; (2) a Hazardous Permit Management; (3) a Hazardous Materials Management; (4) a Human Resource Management; (5) a Hazardous Waste Management; (6) a Hazardous Commitment Management; (7) an Emergency Management Function; (8) a Facility Management Function, operated by a regulatory agency or regulated facility; and (9) a relational database schema or database design 91 that links and fuses the many or all of functional groupings into a single, integrated entity. While we could examine the individual functional groupings described by Sturgeon, such an exercise seems pointless in this Response since the Sturgeon groupings have nothing to do with Applicant's invention - except to note on the record that Applicant's invention involves none of Sturgeons functions, including no management of human resources (function 4: Human

Resource Management). Moreover, Sturgeon states that "[a]ll actions of the above functional groupings are coordinated by the relational data base management system schema that links and fuses the respective individual functional groupings into an information management solution that provides a capability much greater than the sum of the individual parts."

Perhaps, the presence of a relational database management system to coordinate the various functions is why the Examiner selected the Sturgeon patent as a basis for the obviousness rejection – because there seems to otherwise be no basis what-so-ever in the Sturgeon patent for a relationship to Applicant's invention. However, Applicant's invention is not a claim of a first use of a relational database or a relational database management system. In fact, relational databases are well known in the art, and such relational databases have been used in many other management systems. As a result, Sturgeon offers nothing new in this area.

Applicant, therefore, turns to the Office Action itself to determine why Sturgeon is cited as a basis for the Examiner's obviousness rejection. Unfortunately, the Action at page 5 offers no basis or description for the basis for why the Examiner may have relied upon the teachings in Sturgeon – providing only a circular reiteration of Applicant's own claim 201 with the conclusion that "Sturgeon discloses the essential elements of the claimed invention" although Lockhart is relied upon to fill-in the missing element of commercializing new essential adverse event information. As a result, not only does Sturgeon fail to teach or even suggest the basic elements of Applicant's invention, the Examiner offers no reason why one of ordinary skill in the art relying upon Sturgeon (even after the addition of Lockhart) would have any reasonable expectation of success of practicing Applicant's claimed invention. Accordingly the §103(a) rejection must fail because the Examiner has failed to provide evidence supporting a reasonable expectation of success in producing and using the referenced Sturgeon patent.

Inexplicably, the Examiner cites Sturgeon at column 8, lines 23- 25 as support for his conclusion that Sturgeon discloses what is quote as Applicant's own preamble to claim 201. The cited lines, in fact, state:

CHEMMIX offers several programs that determine chemical incompatibilities and potential adverse reactions based upon fire, explosion, heat, toxic gas emission, violent polymerization, flammability, etc.

Nowhere, however, does the Examiner offer any insight into why the cited sentence applies to Applicant's invention, and Applicant can deduce no reason why the Examiner has selected the single sentence in Sturgeon as representative of Applicant's invention. Consequently, without guidance to Applicant, the Examiner's obviousness rejection is unsupported and, therefore, inappropriate. Nevertheless, in an effort to be responsive to the Examiner's rejection, Applicant has conducted an investigation into the methods used by Sturgeon to track a hazardous material, and into what is provided by the cited CHEMMIX program.

The CHEMMIX software cited by the Examiner in Sturgeon appears to no longer be in production or available, making it even more difficult for Applicant to understand the basis for this rejection at the cited section. A Google search revealed only two descriptions of the software (attached hereto as Exhibits 1 and 2), referring to a 1995 DOS-based program. The description of the software (Exhibit 1) states "the program comes with over 3 million reactions between 1700 chemicals." Clearly these 3 million reactions are not "new/novel." Indeed, all are old!

Yet, Applicant's invention as taught by the specification provides a system and methods for screening adverse event information on the basis of "*novelty,*" in terms of patentability. Applicant's Summary at paragraph 0007 states that "[t]he current invention permits not only ways of screening for new, *previously unrecognized adverse events associated with the use of a product or device*, but also a method, system and device for determining which new adverse events and new uses are "essential" (emphasis added). See also paragraph 0040, "One can use the data from the database to compare to previously known adverse events to determine new adverse event information," and paragraph 0076, "Equipped with the new essential adverse information generated by systems 10, 110 and 210, · · ·."

In the cited Sturgeon patent using the CHEMMIX software, once the database of reactions is sold to the software user, the user could not patent these reactions because the reactions would not be "novel" to the users. Furthermore, the concept of identifying

"novel" reactions from "old reactions" is not consistent with the intended use of the CHEMMIX program. The CHEMMIX program is not intended to tell the user if he or she should try to protect exclusive rights to a reaction using a patent; it tells the user only whether the user should make a specific chemical reaction. For example it would be expected that CHEMMIX would warn the user not to mix nitrous acid with glycerin since the resulting product, nitroglycerin, is a highly unstable explosive. This information, however, is not novel, meaning patentable. The discovery that nitrous acid reacts with glycerin was patentable at one time, as were potentially all of the 3 million reactions in CHEMMIX, but that information has been available to the public, and the public can no longer be excluded from practicing such subject matter. Therefore, the 3 million reactions are no longer patentable – and consequently unrelated to, and not suggestive of, a key requirement of Applicant's invention. *See, e.g., Verdegaal Bros., Inc. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1054 (Fed. Cir.), *cert. denied*, 484 US 827 (1987) ("It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable."); *In re Spada*, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition.").

Even if CHEMMIX did have artificial intelligence, which it does not, there is no indication that CHEMMIX provides information on how many users have made a specific inquiry about a specific mixture. The CHEMMIX software would have to utilize a central database to determine if a user is the first to "identify" a new adverse event for a mixture, but as described in Exhibits 1 and 2, CHEMMIX is a PC based tool with no central database. Consequently, if there were hundreds of users, several users could create a profile for the same mixture. The profile would only be "new" for the first user who analyzed the mixture, and no provision is made to determine this information. Nevertheless, Sturgeon offers no suggestion at column 8, lines 23- 25 or anywhere else, that CHEMMIX contains artificial intelligence or that it could predict reactions and adverse events that have never been discovered by traditional scientific methods.

Perhaps the Examiner has relied upon the cited sentence because it refers to the prediction of "potential adverse events" ("CHEMMIX offers several programs that

determine chemical incompatibilities and potential adverse reactions · · ·.") Notably the cited sentence is the only reference to adverse events in the entire Detailed Description of the Sturgeon patent. Therefore, the Examiner appears to be relying entirely upon the provisions of the disclosed CHEMMIX software to provide any basis for determining a potential adverse event.

Although the Examiner has not provided Applicant with a CHEMMIX manual that may have been published 11 years ago, the description of CHEMMIX (Exhibit 2) states that "many of which [CHEMMIX modules] are repackaged EPA programs." Since CHEMMIX was designed to help chemists comply with EPA guidelines it makes sense that CHEMMIX would use the methods that the EPA recommends. Two guidance documents from the EPA (Exhibit 3: Guidance in 1986; Exhibit 4: Guidance in 2001) spell out the steps and equations that the EPA believes should be used to determine potential adverse events. In Figure 2.1 (Exhibit 4) the EPA classifies: Mixtures where there is "data adequate" "not adequate." The point is that the EPA admits that there is no artificial intelligence system for discovering "new adverse events." Thus, the potential for adverse events according to the EPA is predicted, based on prior discoveries of adverse events that have occurred using the same or similar mixture. For example, if a strong acid has caused the release of a toxic fume from a second agent, then it would be predicted (and obvious) that a newly discovered strong acid in the same family would have the same effect.

The program as set forth in the CHEMMIX website reads as follows:

> CHEMMIX (Exhibit 1): Determines the effects of combining chemicals with other chemicals, or with water. An unlimited number of chemicals can be analyzed, and the program comes with over 3 million reactions between 1700 chemicals. Additional chemicals can be added by users. This software can be used to alert users of a number of potential hazards, compatibility determinations, emergency response plans, contingency plans, spill response, and chemical shipments. The next update is expected in the fourth quarter of 1995.
>
> The software is available in IBM (DOS, 384 KB RAM, 3 MB free disk space) and Macintosh (1 MB RAM, 3 MB free disk space) formats.
>
> The cost of the software is $395.

However, no update appears on the web in 1995, or anytime after that date, so it appears that the CHEMMIX software has not been updated, or perhaps it is no longer maintained.

As shown in Exhibit 2, the supplier announces various systems, many of which are repackaged EPA programs. Spreadsheet templates, and other software are included for dispersion modeling, VOC calculations, landfill air emissions, air emissions modeling, waste minimization, and others. CHEMMIX is a chemical reaction software program that determines outcomes of various chemical reactions and has a reporting feature, although it would be of no use in practicing Applicant's invention.

See Exhibit 4, page 6-7: 2.2. PROCEDURE FOR SELECTING A RISK ASSESSMENT METHOD

2.2.1. Introduction

> The 1986 Guidelines for the Health Risk Assessment of Chemical Mixtures (U.S. EPA, 1986) (Appendix A) recommend three approaches to quantitative health risk assessment of a chemical mixture, depending upon the type of available data. In the first approach, toxicity data on the mixture of concern are available; the quantitative risk assessment is done directly from these preferred data. In the second approach, when toxicity data are not available for the mixture of concern, the Guidelines recommend using toxicity data on a "sufficiently similar" mixture. If the mixture of concern and the proposed surrogate mixture are judged to be similar, then the quantitative risk assessment for the mixture of concern may be derived from health effects data on the similar mixture. Finally, the third approach is to evaluate the mixture through an analysis of its components, *e.g.*, using dose addition for similarly acting chemicals and response addition for independently acting chemicals. These procedures include a general assumption that interaction effects at low dose levels either do not occur at all or are small enough to be insignificant to the risk estimate. The Guidelines recommend the incorporation of interactions data when available, if not as part of the quantitative process, then as a qualitative evaluation of the risk.
>
> No single approach is recommended in this guidance document. Instead, guidance is given for the use of several approaches depending on the nature and quality of the available data, the type of mixture, the type of assessment being made, the known toxic effects of the mixture or of its components, the toxicologic or structural similarity of mixtures or of mixture components, and the nature of the environmental exposure. The approaches presented herein represent a mix of well-known, routine methods with several newer, less well-

> established techniques. As a collection, they provide the risk assessor with a number of reasonable options for evaluating risk for chemical mixtures.

Unfortunately, however, even given what we now know about the CHEMMIX disclosure, Applicant can find no relevance for the CHEMMIX software to Applicant's invention, and respectfully ask the Examiner for guidance as to *why* it was cited by the Examiner for the purpose of rejecting Applicant's invention as unpatentable when viewed in light of Lockhart.

Returning then to Sturgeon, the reference is simply irrelevant to Applicant's invention. Applicant does not provide an integrated system for managing activities for handling hazardous substances, or any other substance or service; nor does it provide human resource management, such as training, or emergency management or facility management. In fact, nothing in Sturgeon is remotely related to Applicant's methods for using data associated with a database in which essential adverse event information is stored and based on an analysis of previously gathered data, and identifies at least one "new" useful characteristic or use for a product or device in light of a "new essential adverse event" associated therewith.

B. Obviousness Rejection Combining Sturgeon and Lockhart.

In an attempt to compensate for the deficiencies in Sturgeon's ability to teach Applicant's invention, the Examiner has added Lockhart, stating that "Lockhart discloses commercializing new essential adverse event information stored therein." But, in fact, Lockhart does not teach commercialization of "new adverse event information." The Lockhart patent pertains to granting access to information – but the information is not "new" adverse event information – to which the Examiner may say that the type of information that is commercialized is irrelevant to the effectiveness of the reference as secondary art. But, in fact, it does matter - because the information discussed in Sturgeon was discovered by someone else; thus it cannot be "new." The preparation and promulgation of Materials Safety Data Statements (MSDS) that Sturgeon teaches are generated by others and publicly available by law. Therefore, they cannot be new/novel/patentable, regardless of their commercialization, even if that were suggested by Lockhart. In other words, even after the cited references are combined – neither provides guidance to the skilled artisan relating to "new" adverse event data.

Consequently, even together, the references fail to disclose an important and express element of Applicant's invention. Thus, the combined references cannot teach Applicant's invention, and fail to provide an adequate basis for the Examiner's obviousness rejection.

In Lockhart's disclosure of commercializing protected content, the protected content could only be "new" if the seller were the first person to have discovered the content. In marked contrast, the practitioner using Applicant's invention have full access to the safety data because, for example, the adverse event information is provided to the FDA or other regulatory agencies, and therefore, is fully available. The difference is that competitors cannot include the "new essential adverse event" data into a product or device to permit commercialization of the new use or characteristic relating thereto as a result of practicing the invention, unless and until they have a license to do so. Thus, the "commercialization" referred to in Applicant's invention is quite different from that provided by Lockhart because the data is already publicly available.

Consequently, with regard to Applicant's claims 201 and 206, Sturgeon fails to teach or imply a data analysis which "identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith," as claimed when "new" is defined as novel as set forth in Applicant's specification. Claim 201 requires "said method comprising commercializing *new* essential adverse event information stored therein," with an emphasis on "new." The specification clearly defines "new" as meaning "novel," as opposed to a reference to that which is previously known or reported (see, *e.g.*, Applicant's paragraphs 0011 and 0040). If someone else has identified the adverse event information, it is no longer "new" as defined in Applicant's specification – such information is then previously known or reported – and hence it cannot be proprietary for the new discovery.

The Sturgeon patent obtains safety information from others – but it does not identify "new" adverse events, regardless of whether the obtained information is commercialized or not. Thus, the addition of Lockhart to provide the commercialization element of Applicant's invention is irrelevant. Therefore, Sturgeon could not, even if combined with Lockhart, commercialize "new" essential adverse event information.

Therefore, since the underlying prior art fails to teach Applicant's invention, the addition of Lockhart cannot fill those deficiencies.

The rejection of claims 203 and 205 must necessarily fail for the same reasons as Sturgeon, even with the addition of Lockhart, failed for claims 201 and 206.

The rejection of claims 206, 227, 241 and 242 fails because the data used by both Sturgeon and Lockhart is not patentable. Consequently, it would not, and could not be obvious for one to attempt to patent (as set forth in Applicant's claims) data provided by others. Sturgeon involves tracking a third party's (*i.e.*, manufacturers) safety data and Lockhart discloses commercializing some one else's proprietary information. Neither teaches the discovery or identification of patentable data, even if combined. Thus, it would be impossible to identify patentable data unless one at least starts with a potentially patentable concept or identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith, wherein "new," expressly means novel. See foregoing discussion. As above, since the underlying prior art fails to teach Applicant's invention, the addition of Lockhart cannot fill those deficiencies.

The rejection of claim 207 also fails with regard to formatting the data relating to at least one new adverse event associated with exposure to, or use of the product or device, or documenting same, because as discussed above, the underlying reference, Sturgeon, does not disclose or teach identifying or discovering "new" essential adverse event information associated with exposure to, or use of, the product or device. As a result, since the underlying prior art fails to teach Applicant's invention, the addition of Lockhart cannot fill those deficiencies.

The rejection of claim 209 also fails because Sturgeon does not teach or identify "new" uses. The Examiner cites Sturgeon column 8, line 23-28 (restricted use), but can only make the rejection by ignoring the fact that, if the reactions are old, as described above, then the uses would necessarily also have been "old." Sturgeon does not, and cannot, teach the finding of "new," meaning novel, uses. Therefore, since the underlying prior art fails to teach Applicant's invention, the addition of Lockhart cannot fill those deficiencies.

The rejection of claims 210, 228 and 243-245 fails for the reasons stated with regard to claim 209, because Sturgeon does not teach or identify "new" (novel) uses, and because the underlying prior art fails to teach Applicant's invention, the addition of Lockhart cannot fill those deficiencies.

The rejection of claims claim 211 fails because Sturgeon does not identify proprietary data, nor can it generate proprietary data, for the reasons already discussed. Sturgeon teaches the management of public information made available by others, specifically by manufacturers. As a result, because Sturgeon fails to teach Applicant's invention, the addition of Lockhart cannot fill those deficiencies.

The rejection of claims 216, 217, 220 and 221 fails because, although Sturgeon does mention non-medical products, that discussion in and of itself is not unique. Since Sturgeon fails to teach Applicant's invention for all of the foregoing reasons, the addition of Lockhart cannot fill those deficiencies.

The rejection of claims 231-234 and 238-240 fails because, as previously explained, Sturgeon does not teach identifying "new" (novel) information or developing safety sheets containing "new" (novel) information. Therefore, the underlying prior art fails to teach Applicant's invention, and the addition of Lockhart cannot fill those deficiencies.

The rejection of claims 235-237 fails because Sturgeon does not teach development of products. Therefore, the addition of Lockhart [col. 1, lines 45-50 and col. 5, lines 30-45] regarding how to get higher returns for the development costs associated with the product or device are irrelevant to, and cannot logically be combined with, Sturgeon, which offers no basis for developing the products to begin with. As a result, because Sturgeon fails to teach developing any product, the addition of Lockhart as to how to get higher returns therefrom, cannot fill those deficiencies as compared to Applicant's invention, since there is no product development to begin with.

The rejection of claim 225 fails for the same reasons as claims 201 and 222, because Sturgeon does not teach developing proprietary new uses or characteristics. It is unclear how the Examiner proposes that one could develop a "proprietary" new use or characteristic of a product or device, since none of the information used by Sturgeon could in any way be considered "proprietary." See the foregoing discussions. Sturgeon

only uses information provided by others. Consequently, because Sturgeon fails to teach Applicant's invention for all of the foregoing reasons, even the addition of Lockhart cannot fill those deficiencies. Accordingly, the cited prior art *as a whole* fails to teach or suggest Applicant's invention, and Applicant respectfully asks that the claims be reconsidered and that this rejection be withdrawn.

C. Obviousness Rejection Combining Sturgeon, Lockhart and Diamond.

In an attempt to make up for the deficiencies of Sturgeon combined with Lockhart to teach Applicant's invention, the Examiner has added US Patent No. 5,386,829 (Diamond) for the rejection of claim 202 under 35 U.S.C. §103(a). In making this rejection, the Examiner relies on Diamond to teach that "a patient is selected from a population of 5000 [col. 1, 50 through col. 2, line 58.]" Therefore, the Examiner has concluded that it would have been obvious to modify the combination of Sturgeon and Lockhart to include an event data source comprising data gathered from at least 5000 subjects and adds Diamond's statement at col. 1, lines 26-50, that medical tests are not always 100% reliable. Nevertheless, even if combined, the prior art proposed by the Examiner still fails to add to Sturgeon a key missing element – Sturgeon fails to teach or suggest a data analysis which "identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith," as claimed when "new" is defined as novel as set forth in Applicant's specification. Claim 202 is dependent on claim 201, which requires "said method comprising commercializing *new* essential adverse event information stored therein," with an emphasis on "new." Applicant's specification clearly defines "new" as meaning "novel," as opposed to a reference to that which is previously known or reported (see, *e.g.*, Applicant's paragraphs 0011 and 0040). If someone else has identified the adverse event information, it is no longer "new" as defined in Applicant's specification – such information is then previously known or reported.

Because the Sturgeon patent obtains safety information from others – but it does not identify "new" essential adverse events – the addition of a commercialization element and a database comprising data from at least 5000 subjects – is irrelevant. Therefore, for all of the foregoing reasons, since the underlying prior art (Sturgeon) fails to teach Applicant's invention, the addition of Lockhart and Diamond combined cannot fill those

deficiencies. No cited prior art reference provides an element of identifying "new" essential adverse event data and relate that to the new use or characteristic of a product or device, regardless of commercialization of the finding or size of the data base. Therefore, even when combined, the cited prior art *as a whole* fails to teach or suggest Applicant's invention, and Applicant respectfully seeks reconsideration and asks that this rejection be withdrawn.

D. Obviousness Rejection Combining Sturgeon, Lockhart and Feldman.

In an attempt to make up for the deficiencies of Sturgeon combined with Lockhart to teach Applicant's invention, the Examiner has added US Patent No. 6,221,851 (Feldman) for the rejection of claims 204 and 244 under 35 U.S.C. §103(a). In making this rejection, the Examiner relies on Feldman to teach time increments of one hour and 5 years [Fig. 2], and therefore, is added to show that drug testing occurs over a long period of time to establish accurate results or that there is a high risk of an adverse event in the test population.

However, the Examiner's rejection fails to consider that, even if combined, the prior art proposed by the Examiner still fails to add to Sturgeon a key missing element as stated with regard to the addition of Diamond above for claim 202. Sturgeon fails to teach or suggest a data analysis which "identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith," as claimed when "new" is defined as novel as set forth in Applicant's specification. Claim 204 and 244 are directly or indirectly dependent on claim 201, which requires "said method comprising commercializing *new* essential adverse event information stored therein," with an emphasis on "new." Applicant's specification clearly defines "new" as meaning "novel," as opposed to a reference to that which is previously known or reported (see, *e.g.*, Applicant's paragraphs 0011 and 0040). Therefore, such information is previously known or reported and no longer "new."

Because the Sturgeon patent obtains safety information from others – but it does not identify "new" essential adverse events – the addition of a time period or the presence of a high risk test population – is irrelevant. Therefore, for all of the foregoing reasons, since the underlying prior art (Sturgeon) fails to teach Applicant's invention, the addition of Lockhart and Feldman combined cannot fill those deficiencies. No cited prior art

reference provides an element of identifying "new" essential adverse event data and relate that to the new use or characteristic of a product or device, regardless of the time period over which the data was acquired or the character of the test population. Therefore, even when combined, the cited prior art *as a whole* fails to teach or suggest Applicant's invention, and Applicant respectfully seeks reconsideration and asks that this rejection be withdrawn.

E. Obviousness Rejection Combining Sturgeon, Lockhart and AAPA.

In an attempt to make up for the deficiencies of Sturgeon combined with Lockhart to teach Applicant's invention, the Examiner has added a reference to "Applicant's admitted prior art (AAPA)" to reject claim 201 under 35 U.S.C. §103(a). Unfortunately, however, the Examiner has not indicted what AAPA is being referred to, nor has Applicant made any admission of prior art. Art has been cited in Applicant's Information Disclosure Statements, but there is no admission associated with those statements indicating that Applicant considers the cited art to be "prior art." It is cited merely in compliance with Applicant's obligation to cite art that was published prior to Applicant's filing date that is of a nature that the Examiner may find relevant in accordance with US patent law. No where, however, has Applicant "admitted" prior art, and the Examiner is challenged to point to Applicant's admission.

Nevertheless, the Examiner is relying on such "prior art" to "include the value of commercializing the at least one new characteristic or use determined from the at least one identified adverse event . . . . for the purpose of determining how much to charge the customer for information contained in the database of adverse drug interactions [col. 6, lines 55-65]." No citation is given as to where in the "prior art" the Examiner is quoting. However, the Examiner does cite Applicant's paragraph 113. Therefore, in response Applicant's point out that paragraph 113 (see below) means that in the presence of the current disclosure one skilled in the art could figure out the value of the proprietary information created using Applicant's invention to generate proprietary information.

> [0113] In a preferred embodiment of the invention, a product or device for which an essential adverse event is discovered, is also one that is highly profitable, but would face a marked decrease in profitability if the product or device were to lose its proprietary status. One skilled in the art can screen products or devices by recognized methods to determine the potential value of discovering proprietary essential

> adverse events. Those skilled in *e.g.*, sales, marketing, licensing, statistics or business practices, will know how to use recognized methods to calculate or estimate such parameters as, in the non limiting examples of, current market share, potential market share, total market share in unit volume or sales, marketing costs, elasticity of demand, cost of production, cost of marketing, number of competitors, market potential, cost of discovering a new adverse event, product liability costs, growth of market and the like. Mathematical modeling, with or without the use of computers, can be performed to evaluate whether it would be profitable to develop a proprietary essential new use based on an essential new adverse event. In addition to profitability, an entity may desire to determine cost of capital and opportunity costs before deciding to move forward with the project.

However, as stated above, Sturgeon does not, and cannot teach generating proprietary information because its basis is databases of publicly disclosed data from the manufacturers. It does not teach or lead to valuing of patentable information. Moreover, it is not obvious to Applicant how or why the Examiner believes that one could commercialize another person's or company's non-copyrighted work product in which the originator provides the information for free, as in Sturgeon. Nor is it obvious to Applicant how the Examiner believes that this could be done, or why one would try to commercialize such known and publicly available information. As has been previously argued, Sturgeon fails to teach or suggest a data analysis which "identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith," as claimed when "new" is defined as novel as set forth in Applicant's specification. Applicant's specification, on the other hand, clearly defines "new" as meaning "novel," as opposed to a reference to that which is previously known or reported (see, *e.g.*, Applicant's paragraphs 0011 and 0040). Therefore, such information is previously known or reported and no longer "new."

Because the Sturgeon patent obtains safety information from others – but it does not identify "new" essential adverse events – only the addition of "prior art" that could fill that gap could be relevant. However, no such art has been cited. Therefore, for all of the foregoing reasons, since the underlying prior art (Sturgeon) fails to teach Applicant's invention, the addition of Lockhart and other unnamed "prior art" combined cannot fill those deficiencies. No cited prior art reference provides an element of identifying "new"

essential adverse event data and relate that to the new use or characteristic of a product or device. Therefore, even when combined, the cited prior art *as a whole* fails to teach or suggest Applicant's invention, and Applicant respectfully seeks reconsideration and asks that this rejection be withdrawn.

F. Obviousness Rejection Combining Sturgeon, Lockhart and Portwood.

In an attempt to make up for the deficiencies of Sturgeon combined with Lockhart to teach Applicant's invention, the Examiner has added US Patent No. 5,950,630 (Portwood) for the rejection of claims 212, 213, 215, 218, 219, 229 and 230 under 35 U.S.C. §103(a). In making this rejection, the Examiner relies on Portwood to teach that "the product is medical [col. 6, lines 55-67]."

However, the Examiner's rejection fails to explain why one would be motivated to modify Sturgeon for tracking medical products, and without a motivation in the references themselves to make such a combination, the addition of Portwood is not permitted. The reference cannot be added simply because Applicant's invention suggests that the subject products may include medical products. Applicant's invention cannot be the blueprint for the addition.

In fact, no one would consider the use of Sturgeon for an invention relating to a useful medical product, including generic drugs, because Sturgeon deals only with hazardous materials. Medical products are not generally considered to be "hazardous materials." Medical products are not regulated by the EPA, nor is there a requirement that they follow EPA guidelines. Sturgeon was specifically designed to assist in helping people comply with EPA requirements. Accordingly, there is no reason why one would modify the Sturgeon reference as suggested by the Examiner.

Nevertheless, even if so combined, the prior art proposed by the Examiner still fails to add to Sturgeon a key missing element as stated above. Sturgeon fails to teach or suggest a data analysis which "identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith," as claimed when "new" is defined as novel as set forth in Applicant's specification. Claims 212, 213, 215, 218, 219, 229 and 230 are directly or indirectly dependent on claim 201, which requires "said method comprising commercializing *new* essential adverse event information stored therein," with an

emphasis on "new." Applicant's specification clearly defines "new" as meaning "novel," as opposed to a reference to that which is previously known or reported (see, *e.g.*, Applicant's paragraphs 0011 and 0040). Therefore, such information is previously known or reported and no longer "new."

Because the Sturgeon patent obtains safety information from others – but it does not identify "new" essential adverse events – the addition of the medical nature of the product – is irrelevant. Therefore, for all of the foregoing reasons, since the underlying prior art (Sturgeon) fails to teach Applicant's invention, the addition of Lockhart and Portwood combined cannot fill those deficiencies. No cited prior art reference provides an element of identifying "new" essential adverse event data and relate that to the new use or characteristic of a product or device, regardless of whether the product under consideration is medical or non-medical, or whether the medical product refers to a generic drug. Therefore, even if the references had been properly combined, which they have not, the cited prior art *as a whole* fails to teach or suggest Applicant's invention, and Applicant respectfully seeks reconsideration and asks that this rejection be withdrawn.

G. Obviousness Rejection Combining Sturgeon, Lockhart and Tipton.

In an attempt to make up for the deficiencies of Sturgeon combined with Lockhart to teach Applicant's invention, the Examiner has added US Patent No. 6,097,995 (Tipton) for the rejection of claims 222-224 and 246 under 35 U.S.C. §103(a). In making this rejection, the Examiner relies on Tipton to teach that labeling would notify a user of the at least one new essential event for the product or device [Fig. 100].

However, the Examiner's rejection fails to consider that, even if so combined, the prior art proposed by the Examiner still fails to add to Sturgeon a key missing element as stated above. Sturgeon fails to teach or suggest a data analysis which "identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith," as claimed when "new" is defined as novel as set forth in Applicant's specification. Claims 222-224 and 246 are directly or indirectly dependent on claim 201, which requires "said method comprising commercializing *new* essential adverse event information stored therein," with an emphasis on "new." Applicant's specification clearly defines "new" as meaning "novel," as opposed to a reference to that which is previously known or reported (see, *e.g.*,

Applicant's paragraphs 0011 and 0040). Therefore, such information is previously known or reported and no longer "new."

Because the Sturgeon patent obtains safety information from others – but it does not identify "new" essential adverse events – the addition of labeling – is irrelevant. Therefore, for all of the foregoing reasons, since the underlying prior art (Sturgeon) fails to teach Applicant's invention, the addition of Lockhart and Tipton combined cannot fill those deficiencies. No cited prior art reference provides an element of identifying "new" essential adverse event data and relate that to the new use or characteristic of a product or device, regardless of whether labeled or not. Therefore, even if the references had been properly combined, which they have not, the cited prior art *as a whole* fails to teach or suggest Applicant's invention, and Applicant respectfully seeks reconsideration and asks that this rejection be withdrawn.

Conclusion

In sum, as the courts repeatedly have held, for example, in *Fromson v. Advance Offset Plate, Inc.*, 225 USPQ 26 (Fed. Cir. 1985), and in may other cases, "whether one seeks to modify a single prior art reference, or combine a plurality of prior art references to result in a claimed invention, there must be some suggestion in the prior art as a whole for making the modification or combination." Therefore, before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). Conspicuously missing from the present record, however, is any evidence, other than the PTO's speculation (if that can be called evidence) that one of ordinary skill in the data processing and analysis art would have been motivated to modify the Sturgeon automation, integration, management and regulatory review of environmental, health and safety information as it pertains to the manufacture, process, use, handling, and/or transport of chemical products and/or by-product wastes that are considered hazardous to humans or to the environment (Sturgeon), particularly using the CHEMMIX software cited by the Examiner – to arrive at Applicant's claimed invention. Moreover, the suggestion to so modify Sturgeon and

the knowledge of how to make the modifications cannot come from Applicant's invention. *See, In re Oetiker*, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992). Thus, Applicant respectfully points out that for all of the foregoing reasons, the PTO has failed to established a *prima facie* case of obviousness of any of Applicant's claims by any combination of the cited art, and thus it has not shifted the burden to Applicant to provide unexpected results or other objective evidence of non-obviousness. The notion, therefore, that combination claims can be declared invalid merely by finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute. *Panduit Corp. v. Dennison Manufacturing Co.*, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987).

Thus, having reviewed each of the Examiner's arguments as relating to the cited references, even when viewed in combination, Applicant respectfully submits that there is no combination of cited prior art that teaches Applicant's invention *as claimed.* Applicant's invention is not obvious in view of any cited reference or any combination thereof. It is respectfully submitted, therefore, that all of Applicant's pending claims are in condition for allowance, and Applicant respectfully requests that allowance be granted at the earliest date possible. Should the Examiner have any questions or comments regarding Applicant's amendments or response, the Examiner is asked to contact Applicant's undersigned representative at (215) 988-2700.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573. A duplicate copy of this Amendment and Response is enclosed.

Respectfully submitted,

Date: July 11, 2006

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